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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,850	11/02/2001	Sreekumar Pillai	J6673(C)	6359

201 7590 02/26/2004

UNILEVER
PATENT DEPARTMENT
45 RIVER ROAD
EDGEWATER, NJ 07020

EXAMINER

TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/003,850

Applicant(s)

PILLAI ET AL.

Examiner

Russell Travers, J.D., Ph.D

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The amendment filed November 11, 2003 has been received and entered into the file.

Applicant's arguments filed November 11, 2003 are moot in view of the newly presented rejections. Those rejections herein presented are necessitated by the amendments of November 11, 2003.

Claims 1-2 and 5-6 are presented for examination.

Applicant's election with traverse of Group I, claims 1-2 and 5-6 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the search and examination would not place an undue burden on Examiner. This is not found persuasive for two reasons. First, cancellation of the non-elected claims render the restriction moot. Second, the presented claims are linked only by those compounds taught as useful in Applicants' specification for practicing the invention as envisioned. To meet those claims herein presented Examiner need only provide motivations linking such claims, not those uses envisioned by the Applicants. Thus, the presented claims are broader than envisioned by Applicant and would place an undue burden on Examiner.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

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matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-2 and 5-6 are rejected under 35 U.S.C. § 103 as being unpatentable over Cohen et al, Sichak and Weidenboerner (337) et al, in view of Soares et al, of record or newly cited.

Cohen et al, Sichak et al and Weidenboerner et al, teach the claimed compounds retinoic acid, vanillins (see especially column 2, and claim 1) and isoflavones (phytoestrogens), respectively as old and well known in combination with various pharmaceutical carriers and excipients in dosage forms. These medicaments are taught as useful for treating fungal infections. Claims 1-2 and 5-6, and the primary references, differ as to:

- 1) the concomitant employment of these medicaments,
- 2) administration levels of the medicaments, and
- 2) administration of the medicaments in separate containers.

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It is generally considered prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional anti-fungal agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). Applicant's attention is drawn to In re Dillon, 16 USPQ2d 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known antifungal active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed therapeutic compositions of matter.

Claim 1-2 and 5-6 require a topical pharmaceutical composition, individually packaged to provide those therapeutic benefits inherent in each composition individually. Soares et al employ a dual container system for multi composition use. Those formulations taught by Soares et al employ retinoic acid compositions useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been motivated to employ the dual container dermal administration system

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for the application of dermal medicaments, while enjoying those benefits inherent in sequential application as set forth in *Suares et al* claim 1. The skilled artisan would have seen the separate packaging teachings *Suares et al* useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

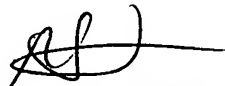
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D., Ph.D whose telephone number is 703-308-4603. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Travers, J.D., Ph.D.
Primary Examiner
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